EXHIBIT 15

MICHAEL R. REED

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In re Bair Hugger Forced
Air Warming Products
Liability Litigation,

MDL No. 14-2666 (JNE/FLN)

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VIDEOTAPED DEPOSITION OF

MICHAEL R. REED

- -

London, United Kingdom

Taken December 4th, 2016 By Rose Kay

Job No. 115951

APPEARANCES:

THE EXAMINER
Allen Dyer

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By: Jonathan Holl-Allen, Esq.
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- and -
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For Plaintiffs

Also Present: Gerlando Scaffidi, videographer

I N D E X

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communications about published studies.
MR. GORDON: The communications about published studies relate to criticisms of the published studies and the way to respond to and address those criticisms and why things were or were not done on a particular --
THE EXAMINER: Let's look at the e-mails.
MR. GORDON: That is what we are --
THE EXAMINER: Let's get to the e-mails. I am not persuaded at the moment. If you show me relevant e-mails, I may be persuaded.
MR. GORDON: I will get to it, but you know --
THE EXAMINER: No, I am not going to allow this type of questioning to continue, unless you lay a basis with proper e-mail references to this witness. I am simply not going to allow it to continue.
MR. GORDON: That is fine. I appreciate that Mr. Reed is kind of cutting to the chase and getting things out, that I will get to eventually. So I will stick to the documents. I apologize. This is going to take a little bit longer this way.
BY MR. GORDON:
Q. Let's go to the McGovern paper, and I want to focus on the second part of the study, the comparison or the -- what you described as the clinical component.

A. Yes. I would like to speak to you about that.
THE EXAMINER: Well, let's get to it first, where it is; so that those of us who are not familiar with this document can identify it.
A. So 540.
THE EXAMINER: Yes, I have got that. Where in the document are you talking about?
MR. GORDON: I think the discussion begins on page 543 and it kind of intertwines a little bit, but --
THE EXAMINER: Can I suggest, Mr. Reed, that you allow Mr. Gordon to ask his questions and answer them and then before we leave this document, you can make any point you wish to make about it, unless you think it is essential for you to lay down your marker before you answer questions about it.
A. I would prefer to do that, if that is okay.
THE EXAMINER: Fine. Do it that way.
A. So when I was reading this documentation yesterday and going through e-mails, it's clear to me that some of the data on the clinical side of the paper is wrong, slightly wrong. It doesn't affect the conclusion of the paper and there's still a significant difference. But there is, in fact, one more infection in each group.
Now, this was e-mailed to Mark Albrecht and he did

reply to it and, in fact, it's in your documents; the e-mail correspondence. And he says he will put it into the main paper and, in fact, he then says he has put it in the main paper, but unfortunately it's slightly old data that is in the main paper. It does not affect the conclusion in any way, but nevertheless it is not the latest data they have got in there, and I don't know why that is.
THE EXAMINER: If Mr. Gordon points you to that specific section, then you can identify it for us.
A. I will ...
BY MR. GORDON:
Q. I am sure we will get to those details.
Just broadly speaking, the clinical component of it was a retrospective observation analysis of infection data; is that correct?
A. So I mean, the data is collected prospectively. So it is not that we look back. It is collected live. So it is prospective in that sense, but I would say it is opportunistic, because we had made the change and then we looked to see what happened. The data is prospective.
Q. Was the data being collected -- were the data being collected for purposes of doing this study?

A. No. We collect data routinely and we have a surveillance team, so that is essentially nursing staff, of which I think we had three at that time, whose job it is purely to look at infection rates, if you like.
Q. Okay. So just again, in broadbrush terms. You had and have a body of infection data and what this study did was to look back at a particular time period; is that correct?
A. Well, we collect --
MR. ASSAAD: Objection, misstates the prior testimony.
THE EXAMINER: You may answer.
A. We collect the data as we go, if you like, and we have done since probably, I think, 2007/2008.
BY MR. GORDON:
Q. What is the reference on page 533 to --
THE EXAMINER: 543?
BY MR. GORDON:
Q. 543, thank you. For demographic information on relevant risk factors for surgical site infections, SSI, collected for primary hip and knee replacement procedures performed at our hospitals -- hospital during a 2.5-year period starting 1st July, 2008?
MR. ASSAAD: Where are you reading? I am sorry.

A. Rarely, but to get to that point, there is a huge number of surgeries normally as well.
Q. And potentially it could cause death?
A. Yes. Well, it does cause death. I mean, there is a definite association with mortality. It reduces your life span.
Q. Do you consider yourself an expert in peri-prosthetic joint infections?
A. Well, in, you know, the view that I have been invited to the international consensus perhaps, and I do speak frequently on it at meetings. I spoke yesterday in Manchester on it. So yes, I speak quite frequently on it.
THE EXAMINER: And my understanding is that it is not that there is a significant percentage or proportion of infections in this surgery. It is because of the severity of the cost to --
A. Exactly. So it is the severity of the complication which is just game changing for most patients. It is a terrible, terrible complication.
BY MR. ASSAAD:
Q. And do you consider yourself an expert with respect to the causation of peri-prosthetic joint infections?
A. I think "expert" is maybe for someone else to judge, but

I do know a lot about it and I have spent a lot of time researching it.
MR. ASSAAD: We need to go off the record, because of the change of CD.
THE VIDEOGRAPHER: This is the end of tape number 2 in the deposition of Michael Reed. Going off the record at 4:44.
(4:44 pm)
(Break taken.)
(4:49 pm)
THE VIDEOGRAPHER: This is the beginning of tape number 3 in the deposition of Michael Reed. Going on the record at 4:48.
BY MR. ASSAAD:
Q. Mr. Reed, we can agree that you need a bacteria to cause a peri-prosthetic joint infection; correct?
A. Yes.
Q. And we can agree that because of the implant, you need very few bacteria to cause a peri-prosthetic joint infection; correct?
A. Correct.
Q. Contrary to a wound infection, where you might need millions; correct?
A. So if you don't have an implant in situ, then you can

have many, many more bacteria on the wound without getting an infection. So yes, it is much more important when you have got an implant.
Q. So an implant is highly susceptible to a bacteria and the cause of a peri-prosthetic joint infection mainly because of biofilm; correct?
A. Yes, so biofilm is a slime that the bacteria produce that protect it from antibiotics and other mechanisms the body might have to rid the infection. So yes, it is very -- it is driven by biofilm, we think, the difficulties in getting rid of the infection.
Q. And you would agree with me that as a result -- strike that.
You would agree with me that most, if not all of the peri-prosthetic joint infections occur when bacteria gets to the implant during the perioperative period; correct?
A. I am not sure we know that. That's -- but that is sort of an accepted philosophy. But I don't think we know that for sure, in actual fact. But that is the dogma.
THE EXAMINER: You referred to the peri ...?
BY MR. ASSAAD:
Q. Peri, during the surgery.
THE EXAMINER: I see, during the operation.

BY MR. ASSAAD:
Q. When you say that is the accepted philosophy, that is the main consensus among most orthopaedic surgeons; correct?
A. Yes.
Q. And because of the biofilm, it is very difficult to treat these peri-prosthetic joint infections through medication; correct, such as antibiotics?
A. Yes. Essentially you can't get rid of an infection with antibiotics alone.
Q. Because there is no vascularity to the joint?
A. Yes, because -- because bacteria and biofilm become very protected by the slime, and so you need about a thousand times the dose of the antibiotic for it to work, and you can't deliver that much antibiotic to the patient.
Q. Have you heard of the term "chain of infection"?
A. Can you -- can you rephrase that?
Q. Yes, I can actually. Basically, for an infection to occur, you have to have an infectious agent, a reservoir, a portal of exit, a mode of transportation, a portal of entry and a susceptible host. Have you heard that described before?
A. Yes.
Q. And for example, so with respect to the infectious

THE EXAMINER: They were at that time?
A. Yes. So this -- briefly, this is a paper where we asked other hospitals around the country that had changed similarly to us, to get in touch; and then we analyzed their data remotely to see what the complications had been.
BY MR. ASSAAD:
Q. And xarelto does not increase increased particles or bacteria to the surgical site; correct?
A. Correct.
Q. I would like you to refer to page 1556.
(Off the record remarks.)
Q. Now, Mr. Reed, you would agree with me that if someone has a peri-prosthetic joint infection, they would have to be returned to the operating room; correct?
A. Almost certainly. Very rarely not.
Q. Okay. So if you look at this document, you have wound complications using xarelto, as compared to a low molecular weight heparin. And then you have, two below it, return to surgery from infection. Do you see that?
A. Yes.
Q. And do you agree with me that if we are looking at PJIs, we should be looking at the differences between xarelto and the low molecular weight heparin for returning to

surgery for infection; correct?
A. Yes, correct. I just have the caveat that I don't know what timescale this looks at. But it is probably within 30 days, which would be a reasonable thing to look at.
(Off the record remarks.)
Q. So would you agree with me that the change from the low molecular weight heparin in the McGovern study to xarelto in the return had no effect; it was not a confounding factor with respect to the infection rates?
A. So based on this study of 12,000 patients, I would say there was no effect on return to surgery from infection.
Q. So would you agree with me that based on this study, that you are an author of, that looking at the date of the McGovern paper, that now we can exclude xarelto as a confounding factor for infection rates?
A. I think that's what this paper says.
THE EXAMINER: Because you nevertheless thought it appropriate to refer to the change in the McGovern paper.
A. Yes, because in our paper, there wasn't a significant difference in infection rates. But there was a signal; that was -- so that's why I put it in. It is safer to be upfront and fair about it.

BY MR. ASSAAD:
Q. And we had a discussion today about the unidirectional airflow in the operating rooms; correct?
A. Yes.
Q. And you believe that it prevents -- using unidirectional flow prevents peri-prosthetic joint infections?
A. Yes.
Q. Because it reduces the particles in the operating room; correct?
A. Yes.
Q. There is an argument that has been made with respect to critiquing your McGovern article, that laminar flow actually increases peri-prosthetic joint infections. Have you heard that argument before, regarding your article?
A. Yes.
Q. And you are of the opinion that, in fact, that needs to be looked at, because you think the forced air warming has an effect on the laminar unidirectional airflow; correct?
A. Yes. I think it may have an effect on that data.
Q. And actually you have written about that in the book chapter published in 2016; correct?
A. Yes, very likely.

Q. We have also discussed keeping patients warm during the preoperative and perioperative period; correct?
A. Yes.
Q. And you believe one or the other is fine; correct? Or I could have misunderstood you.
A. Well, it's not -- you haven't misunderstood me, but I think in terms of where the evidence is, I think that's possibly where the evidence is; one or the other is fine. But I would say the best practice now is to do both. And in fact, the NICE guidance draft, which has just come out, will be to do pre-warming and warming during surgery.
Q. But you agree that there's no evidence, scientific evidence, that indicates that keeping a patient warm during surgery and before surgery reduces peri-prosthetic joint infections?
A. So do -- okay. So there's definitely evidence that in colorectal surgery, that keeping people warm reduces their infection rate. And there is evidence from David Leaper's study, who you are going to meet, that pre-warming patients reduces infection rates in their clean surgery. But that is not during the operation. That is before.
I would say there isn't any evidence that doing